

REMARKS

The Specification has been amended to include continuity data. Claims 30, 34, 40, 41, and 47 have been amended. Claim 50 was inadvertently listed as being canceled by the Applicant rather than being withdrawn as being drawn to a non-elected species as intended. However, Applicant reserves the right to pursue the subject matter of claim 50 in a related application. Claim 43 has been canceled. Claims 32, 33, 49, and 51-63 are withdrawn. New Claim 64 has been added. Support for the new claim can be found in the Specification as filed, on page 24, lines 1-3 and page 28, lines 9-22. As a result, Claims 30, 31, 34, 40, 41, 44, 45, 47, and 64 are presented for the examination.

Claim 30 has been amended to include the terminology "digital video disc." During the telephonic interview on May 24, 2004 the Examiner agreed to this amendment and that this terminology is supported by the specification.

Claim 30 has also been amended to recite that the CD or DVD does not contain microchannels. This amendment is supported in the specification at page 14, lines 3-7. In particular, Applicant notes that, while some embodiments of the present invention can include microchannels, Applicant is not claiming those embodiments in the presently amended claims. Applicant reserves full rights to pursue those embodiments in later filed applications. Applicant notes that, as discussed in the telephonic interview, the discs in the Virtanen reference cited by the Examiner include microchannels.

Claim 30 has also been amended to recite that the CD or DVD is not rotating during the binding step. In Example 1, on page 27, lines 15-229 the Applicant describes hybridization of CMV biotinylated DNA on a CD, which included incubating the conventional CD which does not have microchannels with various solutions for up to 2 hrs. Applicants note that the procedure described in Example 1 is similar to that performed in a traditional hybridization using conventional supports such as nitrocellulose filters. It is apparent that the procedures described in Example 1 would not be performed while the disc was rotating. Similarly, ELISA detection of bovine serum albumin on a CD in Example 3, on page 29, line 25-page 30, line 4 involved incubation of the CD in various solutions for up to 90 minutes. The procedure described in Example 3 is similar to ELISA analyses performed on conventional supports. It is apparent to a skilled artisan that the described method is performed on a non-rotating CD outside the CD-

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reader. Therefore, Applicant asserts that the limitation introduced in currently amended Claim 30 is supported by the Specification as filed.

Claim 30 was further amended to recite that the capture molecules are located on areas of the disc that do not have grooves or registered data. This amendment is supported in the Specification at page 18, lines 8-11 and in Figures 4, 5, and 7.

Claim 30 was further amended to recite that the target and capture molecules are nucleic acid molecules or proteins. Such amendment is supported in the Specification as filed, for example, in Examples 1-5. The Applicant understands that the examination of the claim is currently restricted to the elected species of nucleic acids per the election in the response to Restriction Requirement filed May 20, 2002. However, upon allowance of the generic claim Applicants will be entitled to additional species, i.e. proteins.

Claim 30 was further amended to recite that the reading of signal resulting from the binding between the target and capture molecules is done when the disc is rotating on its axis, supported in the original Claim 43.

Claim 34 has been amended to recite "a magnetic field". This amendment is supported in the Specification at page 22, lines 22-29 and page 31, line 3 (Example 5 and Figure 7).

Claim 47 has been amended to recite that the registered data are used in the indication of the characteristics of capture molecules upon specific areas of said CD or DVD or the interpretation of the signal which is the result of binding between a target and a capture molecule. This amendment is supported in the Specification at page 5, lines 19-24.

Therefore, no new matter has been introduced by these amendments. The following addresses the substance of the Office Action.

Claim objections

The Examiner has objected to Claim 40 is being improperly dependent on canceled Claim 39. The Applicant has amended Claim 40 to properly depend on Claim 30.

Claim rejections under 35 USC §112

The Examiner has rejected Claims 30, 31, 34, 40, 41, 43-45, and 47 under 35 USC §112, first paragraph as failing to comply with the written description requirement. More specifically, the Examiner interpreted the term "target molecule" as encompassing virtually any molecule. Applicant wishes to remind the Examiner that in response to Restriction Requirement mailed 21 March 2002, Applicant elected for initial examination the species of nucleotides with

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understanding that upon the allowance of a generic claim Applicants will be entitled to consideration of claims to additional species. Applicants have amended the claims to recite embodiments in which the target and capture molecules are nucleic acids or proteins. However, Applicants maintain the right to pursue embodiments in which the target and capture molecules are molecules other than nucleic acids or proteins in related applications.

The Examiner has interpreted the Claims as encompassing performance of any part of the assay, including binding and manipulation of reagents while at the same time having the disc rotate at any speed. The presently claimed method requires only that the reading of the registered data and the reading of the signal resulting from the binding is done when the disc is rotating upon its axis. The binding between the target and the capture molecules is not done when the disc is rotating upon its axis. The currently amended Claim 30 recites that the CD or DVD does not have microchannels and is not spinning on its axis during the binding step (see arguments in support for this amendment above).

The Examiner further has interpreted the claims to encompass a disc where reagents, binding areas and detection areas are located within grooves. The applicant has now amended Claim 30 to specify that the capture molecules are not located in grooves or in the areas of registered data.

The Examiner has requested that the Applicant amend the claims to recite only specific types and sizes of discs which he considers as adequately described in the Specification. Applicant respectfully maintains that the specification explicitly discloses the use of discs of different dimensions or shapes. In particular, these points are discussed in the Specification as filed on page 11, lines 20-31 and page 12, lines 19-30. In addition, as requested by the Examiner during the telephonic interview, Applicant provides evidence (see Appendix 1) that a conventional CD or DVD may be manufactured in any form which allows the rotation of said disc along the central axis, as specifically described in the specification.

The Examiner suggested that because the Specification describes capture molecules located in the grooves as well as outside the grooves on the discs, that the Applicant was not in possession of the claimed invention. Applicant respectfully disagrees. The presence of alternative embodiments does not indicate that the inventor was not in possession of the invention as claimed in the currently pending claims which encompass just one of such embodiments.

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The Examiner has stated that the aspect of encouraging one to "see" a document cited in the specification is not considered an incorporation-by-reference, and therefore the cited documents are not considered a part of the disclosure other than background. Applicants do not assert that the text of the cited references are incorporated into the specification. However, Applicants note that the information in these references is useful in determining what information Applicants were in possession of as of the date the application was filed.

The Examiner has cited Examples 1-5 as not providing enough written description for the two reading devices. Applicant respectfully disagrees.

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had the possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention (see MPEP 2163. I).

Examples 4 and 5 of the present application clearly describe all the characteristics of the method according to the invention. Example 4 refers to a detection of proteins on a CD by laser detection. Figure 5 referred to in Example 4 clearly shows that the step of reading the registered data and the step of reading the signal resulting from the binding between a target and a capture molecule is done by two different reading devices. Indeed, Figure 5 illustrates a first laser directed upon the spinning disc and reading the CD tracks is and that simultaneously a second reading device detects the spot resulting from the binding between the target and the capture molecules, upon the surface of the CD in an area that does not comprise any grooves or registered data. The spot can be read by a method consisting of reflection, absorption and diffraction of a light beam by a light detector. Figure 5 also describes a portion of the CD surface comprising on a first area the CD tracks and fixed on a second area the capture molecules located at the periphery of the CD (see page 28, lines 26-29). Similarly, Figure 7 clearly shows that the CD is being read by two separate reading devices. Therefore, the specification indicates that the disc is placed in a single apparatus with two reading devices, wherein the first reading device is dedicated to the reading of the registered data and wherein the second reading device is dedicated to the reading of the signal resulting from the binding between the target and the capture molecules. Furthermore, one skilled in the art would appreciate that the same methodology can

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be employed for detection upon a CD or a DVD, since a DVD differs from a CD only in the specific type of information encoded (sound vs. image and sound). Therefore, Applicants maintain that the specification contains sufficient description of the invention to support the currently pending claims.

The Examiner is further under the impression that because Example 2 describes a silver staining method and because the binding is interpreted to take place while the disc is spinning, the Specification does not provide enough written description for detecting precipitates of but one molecule to the capture molecule, and further that the Applicant was not in possession of the invention at the time of filing. As discussed above, the Applicant has amended claim 30 to specify that the method according to the invention comprises the step of binding between a target and a capture molecule on a CD/DVD, and the step of treating the CD/DVD in order to obtain a detectable signal (formation of a precipitate on the CD or DVD surface) both of which do not require that the disc is rotating upon its axis. As specified in the present claims, the disc is rotating upon its axis in the apparatus comprising two different reading devices only for the reading of the registered data and the reading of the signal (resulting from the binding). In the examples, as discussed above, the steps of binding, treating and reading the CD or DVD are clearly successive and not simultaneous. Therefore, the applicant asserts that the specification provides enough support for the reproduction of the method according to the invention.

The Examiner further asserted that the Specification does not provide enough support on how to read the registration data subsequent to binding when the CD has been coated with an agent that would limit non-specific binding, as such coating would block the reading of binary data. Applicant wishes to point out that the specification does not require that the CD be coated with an agent that would protect the surface of the solid support. Rather this is simply one embodiment of the invention which provides a protection of capture molecules from oxidation. This possible additional steps is used before the binding of the target molecules and the capture molecules, but would not affect the reading of binary data which is done on a separate surface of the disc (see page 9, line 29 through page 10, line 3, and Figures 5 and 7).

The Examiner has rejected Claim 47 for lack of written description in the Specification of the term "treatment" and "interpretation. The Applicant has now amended Claim 47 to recite that registered data are data used in indication of the characteristics of capture molecules upon specific areas of said CD or DVD or interpretation of the signal which is the result of binding

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between a target and a capture molecule. How such signal is interpreted is well within the scope of a skilled artisan.

The Examiner has rejected Claims 30, 31, 34, 40, 41, 43-45, and 47 under 35 USC §112, second paragraph as being indefinite. More specifically, Claim 1 was rejected for the citation of the term "the detection" which lacks antecedent basis; for using the abbreviation "DVD" without first defining the abbreviation. The applicant has amended Claim 1 to now recite "a detection" and "digital video disc". During the telephonic interview conducted on May 24, 2004 the Examiner agreed to this amendment and that this terminology is supported by the specification. Therefore, Claim 1 is now definite.

Claim 41 was rejected for reciting the term "the fixation", which lacks the antecedent basis. Applicant has amended Claim 41 to now recite "a fixation". Therefore, Claim 41 is now definite.

Claim 47 was rejected for reciting the terms "the treatment" and "the interpretation of the signal", which lack antecedent basis. Applicant has amended Claim 47 to now recite "an indication of characteristics of capture molecules upon specific areas of said CD or DVD or interpretation of the signal which is the result of the binding between the target and the capture molecule", which has a proper antecedent basis in Claim 30.

Claim rejections under 35 USC §103

The Examiner has maintained the rejection of Claims 30, 31, 34, 40, 41, 44, 45, and 47 under 35 USC §103(a) as being allegedly obvious over Virtanen (USP 6,030,581) in view of Rushbrooke et al. (USP 6,263,095). More specifically, the Examiner has maintained that it would have been obvious to a person skilled in the art at the time the invention was made to combine the method of Virtanen for detecting nucleic acid captured by a capture probe immobilized on a surface of a disc such as CD or DVD with the method of Rushbrooke et al. for detecting nucleic acids by imaging means through detection of bound label that emits light. The arguments presented in response to the previous Office Action were not found persuasive because the limitations of the disc being static and not having reaction chambers and fluid channels were asserted to not be present the Claims.

To establish a *prima facie* case of obviousness, the PTO must cite one or more references that provide some suggestion or motivation to modify the references to achieve the claimed invention, provide a reasonable expectation of success to achieve the claimed invention, and

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finally, the cited art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The Applicants have now amended claim 30 to recite that the disc does not comprise microchannels and consists of a CD or DVD support only. Claim 30 was further amended to recite the limitation that the reading of the obtained signal is done when the disc is rotating on its axis. Therefore, Virtanen and Rushbrooke alone or in combination do not teach all the limitations of Claim 30.

Furthermore, the combination of Virtanen and Rushbrooke does not render the claimed invention obvious because fluorescent based techniques are not compatible with conventional CDs or DVDs. The method of detection of the present invention is based upon the reading of a signal resulting from the binding from the target and the capture molecules that forms a precipitate on the CD or DVD surface, preferably an opaque or magnetic precipitate (claim 40) rather than fluorescence. Such signal (precipitate) that can be read easily by a reading device included into an apparatus as proposed in the method of the invention is not described in the state of the art. However, if the detection is based upon fluorescent labels as taught by Rushbrooke et al., such detection is not possible upon a solid support which consists of a CD or a DVD. Indeed, a CD or DVD is made of a polycarbonate which is not adequate for a detection by fluorescent labels due to the very high auto-fluorescent signal as will be shown in the Declaration under 37 CFR 1.132 submitted shortly. The data presented in this Declaration will show auto-fluorescence characteristics of a CD as compared to glass which is known for its absence of auto-fluorescence. The auto-fluorescence is so high for CD that the reading of spots resulting from the binding between target and capture molecules would not be distinguishable from the background. Therefore, Claim 34 has been amended to recite the variation of a magnetic field as the method for detecting the signal resulting from this binding.

In view of the foregoing, Applicant asserts that it is impossible to combine the teaching of the cited art and obtain the method for detection and/or quantification of a target molecule according to the invention as claimed in currently amended claim 30. Accordingly, Applicant respectfully requests that the present rejection of Claims 30, 31, 34, 40, 41, 44, 45, 47, and 64 under 35 U.S.C. 103 be withdrawn.

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CONCLUSION

In conclusion, the Applicant has addressed all issues raised in the present Office Action. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections and allowance of Claims 30, 31, 34, 40, 41, 44, 45, 47, and 64 is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

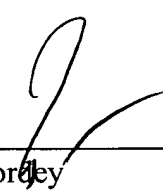
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 6, 2004

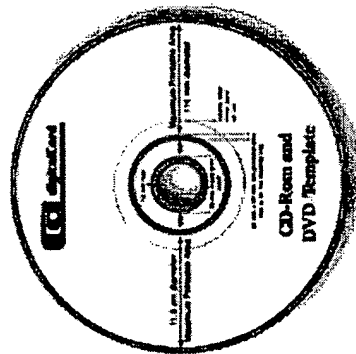
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Marina L. Gordley
Registration No. 52,950
Agent of Record
Customer No. 20,995
(805) 547-5580

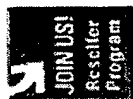
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113004



Specifications & Dimensions



Note: With CDDC molds, you can choose any shape pictured below or we can assist you with designing imaginative custom shapes! CDDC shaped CDs can hold up to 170MB & DVDs up to 1.0GB and will fit securely in the Player tray even if the Disc outer dimensions exceed 80MM. We can give you any capacity with any shape.



The Shapes Below are for CD-Rom & DVD 5, 9 & 10 the capacity shown only for DVD 5 You can double the capacity for DVD 9.



CD-Rom & DVD

Available Sizes
CD & DVD



25-MB(56x86MM)150MB DVD
40-MB(58x86MM)240MB DVD
50-MB(61x86MM)300MB DVD
70-MB(63x86MM)420MB DVD
80-MB(64x88MM)450MB



CD-Rom & DVD



CDDC-01

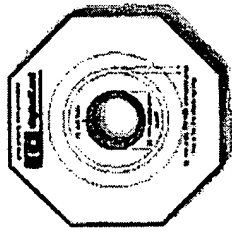
Available Sizes
CD & DVD

56mm-01 25MB/150MB DVD
58mm-01 40MB/240MB DVD
60mm-01 50MB/300MB DVD
62mm-01 65MB/360MB DVD
63mm-01 70MB/420MB DVD
64mm-01 80MB/450MB DVD
66mm-01 85MB/510MB DVD
68mm-01 100MB/600MB DVD
70mm-01 125MB/750MB DVD

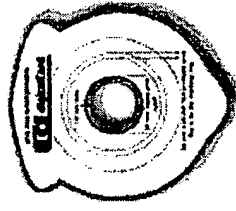
Appendix 1

Rectangle(CDDC Mold)

DVD
90-MB(66x89MM)550MB
DVD
100-MB(68x89MM)
600MBDVD
125-MB(70x89MM)
750MBDVD



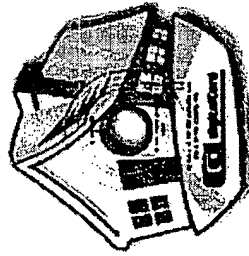
120MB Stop Sign



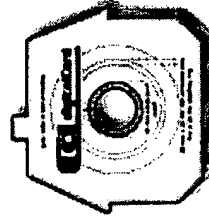
70MB Badge

70-MB CD - 420 MB DVD

120-MB CD - 720MB DVD



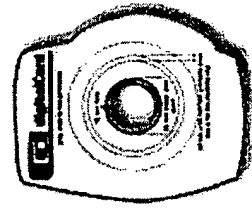
150MB-House (CDDC Mold)



50MB House

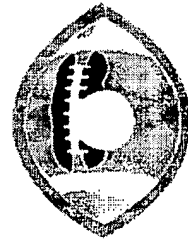
50-MB CD - 300 MB DVD

150-MB CD-Rom/900 MB
DVD

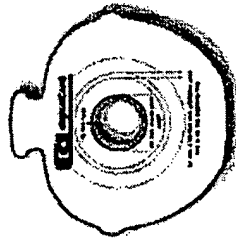


40MB/240MB DVD

40MB/240MB DVD

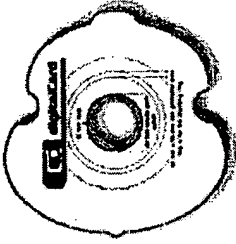


FootBall



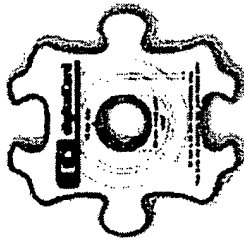
140-MB CD-Rom/840MB
DVD

Beer MUG



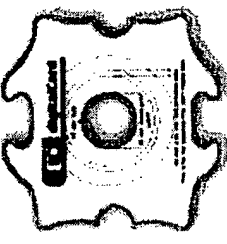
20MB/150MB DVD

Grill (CDDC Mould)



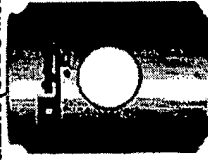
25 MB CD-ROM/150MB DVD

Violin



40MB CD-Rom//240MB DVD

Puzzle (CDDC Mould)



CD/DVD

50-MB (61x90MM)300MB
DVD

70-MB (63x90MM)420MB
DVD

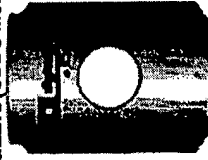
80-MB (64x90MM)450MB
DVD

90-MB (66x90MM)550MB
DVD

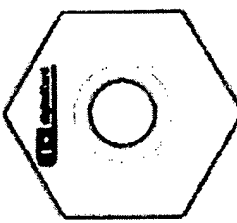
100-MB(68x90MM)
600MBDVD

80MB CD - 450MB DVD

Beverage Can (CDDC Mould)

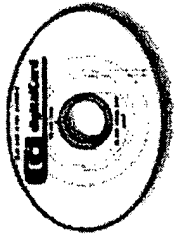


80MB Hexagon

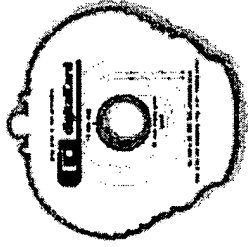


150MB-CD-Rom/900MB DVD

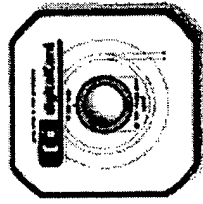
40MB CD - 240MB DVD



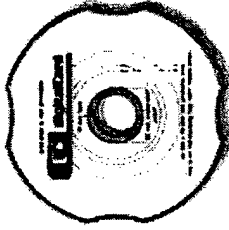
40MB Oval



Crown (CDDC Mold)



58mm Square

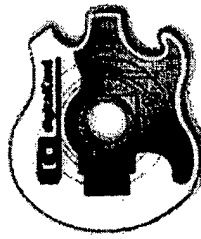


150MB 05

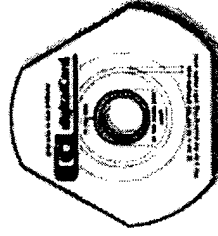
40 MB SQ - 240MB DVD

80MB SQ - 450MB DVD

150MB CD - 600MB DVD



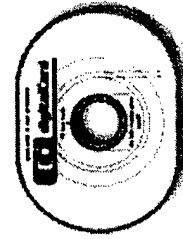
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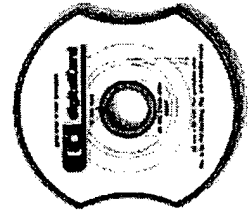
85MB Triangle

40MB CD - 240MB DVD

85MB CD - 500MB DVD


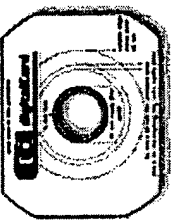
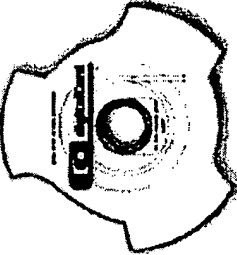
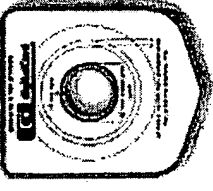
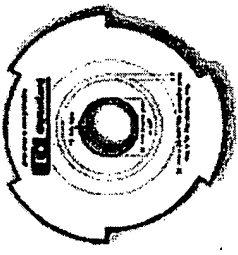
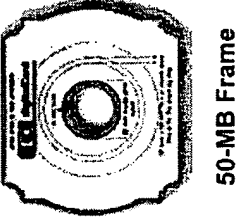


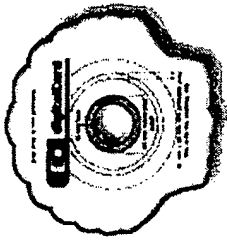
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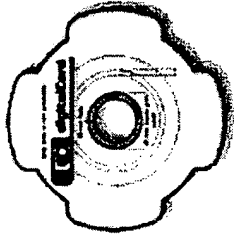
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50MB CD- 300 MB DVD

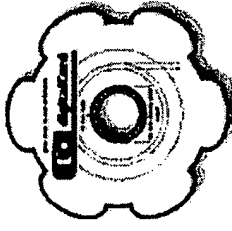
| | | | |
|--|---|---|---|
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|  <p>Center Puzzle</p> |  <p>50MB Shield</p> | <p>50-MB CD- 300- MB DVD D</p> | <p>50MB CD- 300 MB DVD</p> |
|  <p>CDDC-15</p> |  <p>50-MB Frame</p> | <p>120-MB CD- 720- MB DVD D</p> | <p>50MB CD- 300 MB DVD</p> |
| <p>70MB CD - 400 MB DVD</p> | <p>85MB - 500 MB DVD</p> | <p>85MB - 500 MB DVD</p> | <p>85MB - 500 MB DVD</p> |



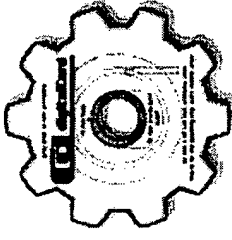
70MB Clam Shell



85MB-10



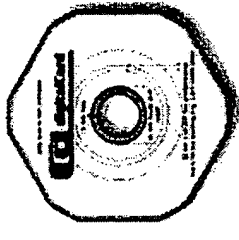
85MB-11



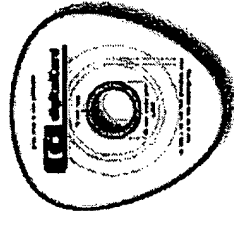
90MB Cog



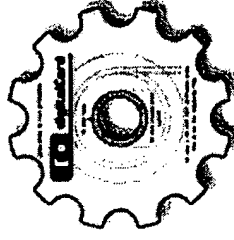
40MB-14



150MB-04



60MB Guitar Pick



85MB Sprocket

85MB CD - 500 MB DVD

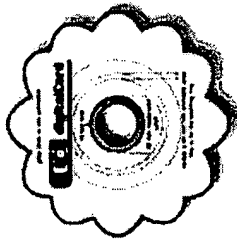
90MB CD - 550MB DVD

40MB CD - 240MB DVD

150MB CD - 600MB DVD

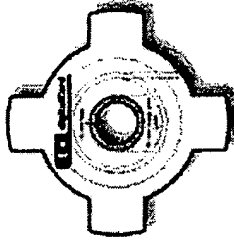
60MB CD- 360MB DVD

85MB CD- 500MB DVD



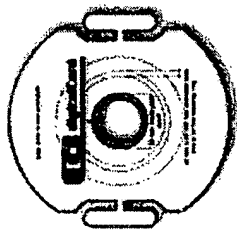
65MB MiniFlower

65MB CD- 390MB DVD



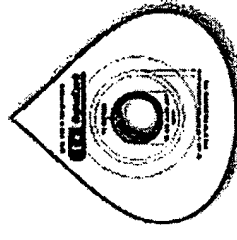
40MB MiniCross

40MB CD- 240MB DVD



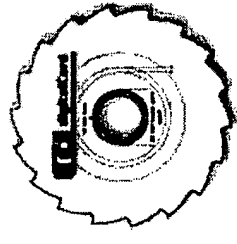
40MB E-Ticket (2Tab)

40MB CD- 240MB DVD



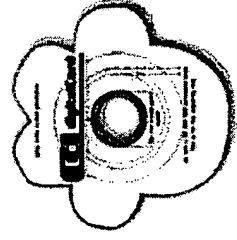
150MB- Water Drop

150MB CD(cddc Mold)



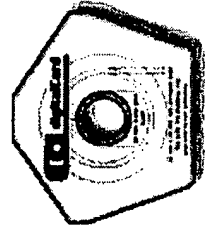
140MB Rip Saw

140MB CD- 800MB DVD

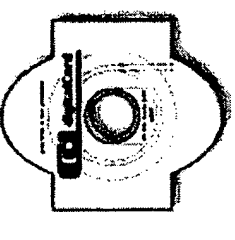


40MB Paw

40MB CD - 240MB DVD

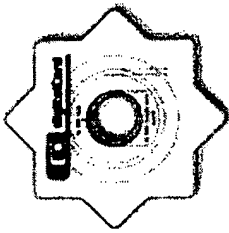


40MB CD - 240MB DVD

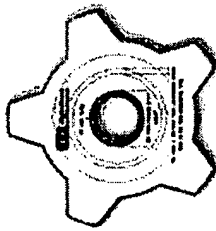


50MB CD - 300MB DVD

40 MB Polygon



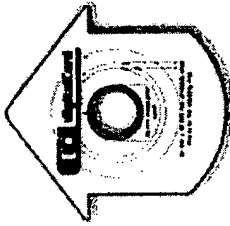
50MB Star 01



40MB Star Ring

50MB-12

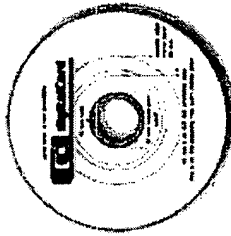
50 MB CD - 300 MB DVD



40MB Arrow 02

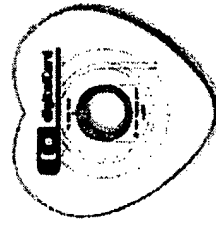
40MB CD - 240MB DVD

40MB CD - 240MB DVD



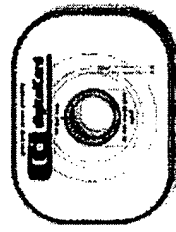
185MB CD - 1.1GB DVD

80mm(3") Mini



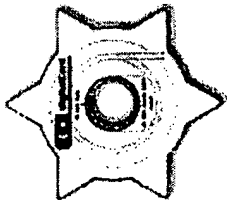
40MB Heart

40MB CD - 240MB DVD



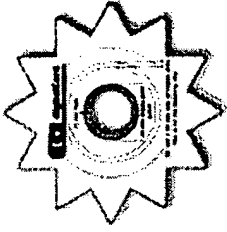
30MB CD - 195MB DVD

57mm Rectangle



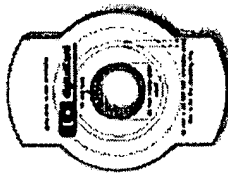
40MB Star 03

40MB CD - 240MB DVD



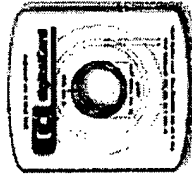
40MB Star 05

40MB CD - 240MB DVD



40MB Keyhole

50MB CD - 300MB DVD



58mm Can

40-MB CD - 240MB DVD



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